CDER GUIDANCES

NEW/REVISED/WITHDRAWN

1/1/2006 –1/31/2006

(Sorted by date)

Title	Subject	Level at Date of Issue	Publication/ Withdrawal Date	Status
Recommended Approaches to Integration of Genetic Toxicology Study Results	Pharmacology Toxicology	Level 1	01/04/2006	New
M2: eCTD Specification Questions and Answers and Change Requests	Joint Safety/Efficacy	Level 2	01/06/2006	New
Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice	CGMPs	Level 1	01/12/2006	New
Exploratory Investigational New Drug Studies	Pharmacology Toxicology	Level 1	01/17/2006	New
Investigational New Drugs; Approaches to Complying with Current Good Manufacturing Practice During Phase 1	CGMPs Draft	Level 1	01/17/2006	New
Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products — Content and Format	Labeling	Level 1	01/24/2006	New
Clinical Studies Section of Labeling for Human Prescription Drug and Biological Products — Content and Format	Labeling	Level 1	01/24/2006	New
Labeling for Human Prescription Drug and Biological Products — Implementing the New Content and Format Requirements	Labeling Draft	Level 1	01/24/2006	New
Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products — Content and Format	Labeling Draft	Level 1	01/24/2006	New